MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Checklist for Submission Clinical Trials Applications for Authorization

Clinical Trial Tittle; .....

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No.	Item	Yes/No
1.	Cover letter	
2.	Completed application form	
3.	The Study Protocol	
4.	Patient Information leaflet and Informed consent form	
5.	Investigators Brochure/Package inserts	
6.	Investigational Medicinal Product Dossier	
7.	Stability data of the investigational product supporting the intended shelf life of the product	
8.	GMP certificate of the investigational product from the site of manufacture	
9.	Certificate of Analysis of the investigational product	
10.	Pictorial Sample of the investigational products. This sample should include the text of the labeling to be used	
11.	Signed investigator(s) CV(s) including that of study Pharmacist. **The CV should include the current workload of the Principal Investigator**	
12.	Evidence of contractual agreement between sponsor and Principal Investigator	
12.	Evidence of recent GCP training of the core study staff	
13.	DSMB Charter including the composition and meeting schedule	
14.	Detailed budget of the study	
15.	Financial declaration by Sponsor and/or PI	

No.	Item	Yes/No
16.	Indemnity cover for PI and other investigators	
17.	Clinical Trials Insurance Cover for the study participants	
18.	Copy of favorable opinion letter from the local Ethics Review Committee (ERC).	
19.	Copy of current Practice Licenses for the Investigators and study Pharmacist	
20.	Copy of approval letter(s) from collaborating institutions or other regulatory authorities, if applicable	
21.	Statistical Analysis Plan	
22.	Where the trial is part of an international study, sufficient information regarding the other participating countries and the scope of the study in these countries.	
23.	For multicenter/multi-site studies, an addendum for each of the proposed sites including among other things the sites' capacity to carry out the study i.e. personnel, equipment, laboratory etc	
24.	Registration of the clinical trial in the registry at www.ctr.pharmacyboardkenya.org	
25.	A signed statement by the applicant indicating that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading and that the study will be carried out according to protocol and applicable laws and regulations.	
26.	Payment of fees	
27.	Four bound hard copies of all the above	

N/B All submitted documents should be signed, dated and version referenced if applicable.

Signed

Applicant Name…… Sign…….. Date……

PPB Staff Name …… Sign…….. Date……